COMPARISON OF TWO METHODS OF OBTAINING DIGITAL ORTHODONTIC MODELS: DIRECT VS. INDIRECT

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DEDICATION

This thesis is dedicated to my family. The hours of work which are necessary to learn the art and science of orthodontics often come at the expense of those I care about most. Thank you to my wife, Jennifer, and son Eli for daily encouragement and understanding. Thank you to my parents, Joseph and Barbara Parris for believing in my ability and providing every opportunity to succeed.

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ABSTRACT

Introduction: Advancements in the application of technology have been progressing at an unprecedented rate in the field of orthodontics. One area in which technologies are constantly evolving is in the production of digital orthodontic models for both treatment planning purposes as well as the fabrication of orthodontic appliances. The purpose of this study is to compare linear measurement accuracy on three-dimensional digital orthodontic models obtained by direct scanning to those obtained by indirect scanning. **Methods**: A resin model with reproducible occlusion was fabricated and used as the control. Three dimensional digital orthodontic models were produced both by direct scanning of the control model and indirect scanning using a PVS impression and bite registration. Inter-arch and intra-arch linear measurements were made. The percent change from the control model for each scanning method was evaluated. **Results**: Analysis revealed a statistically significant difference in linear measurement accuracy for both scanning methods when compared to the original model control. Overall, the iTero iOC direct scan was found to be more accurate and reliable than the ESM R700 indirect scan. Three of the five inter-arch measurements were found to be significantly more accurate and displayed a smaller standard deviation at every measurement location. Also, it was found that the intra-arch measurements tended to be more accurate and reliable for both scanning methods. **Conclusions**: The larger inter-arch differences were most likely due to inaccuracies in the digital articulation of the models using the bite

registration material when utilizing the indirect method. In conclusion, the larger inaccuracies are most likely not clinically significant. This study suggests that digital models produced by direct scanning are more accurate for not only diagnosis and treatment planning but fabrication of orthodontic appliances. If the appliance involves both the maxillary and mandibular arches, the inaccuracy is increased.

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I. BACKGROUND AND LITERATURE REVIEW

A. Background

Since the dawn of the profession, the standard for three dimensional orthodontic study models has been a set of maxillary and mandibular white stone casts trimmed to orthodontic specifications. These models have served orthodontists both as a way to document the starting positions of their cases, and also as an aid in diagnosis and treatment planning decisions. Accurate models are a key component to the standard of care acknowledged for orthodontic treatment planning and case assessment (Jerrold, 2006). Until recently, this has involved a clinical procedure in which acceptable impressions of the teeth, gingiva and surrounding tissues are made, followed by a lab procedure in which the negative impressions are turned into a positive reproduction of the areas impressed.

There have been many studies in which the accuracy of impressions and subsequent models has been examined. Due to the technique sensitivity of the impression making process and properties of the materials, there are many variables which contribute to the overall accuracy of the final study models. In a study by Downey et al in 2006, several different impression materials were used to fabricate study models. These impressions were then poured either immediately or after 3 days. Additionally, the impressions which were held for 3 days were separated into three distinct temperature groups (-17Deg C, 20 Deg C, and 60 Deg C) for storage prior to pouring. It was found that all impression

materials are able to produce a clinically acceptable model under normal conditions but that low temperature storage of the impressions led to less dimensional stability. In another study by Alcan et al. in 2009, the dimensional accuracy of alginate impressions was studied by pouring impressions into stone models after one to four days and then scanning the stone models to create digital models. While significant differences were found in the measurements made on the digital models, it is speculated that these differences would not be clinically relevant. In a similar study by Dalstra et al in 2009, alginate impressions were taken of a dental model and poured either immediately or after a 3-5 day shipping procedure. When digital models were created from scans of the plaster models, no significant differences were found between those poured immediately and those poured after the 3-5 day transit time. When using a scanning device in order to create a digitized orthodontic model from an impression, it is important to consider the accuracy of the impression materials. In a study performed by Shah et al in 2004, both polyether (Impregum) and Polyvinyl siloxane were able to create digital models which were within one standard deviation from the mean, suggesting that the accuracy of most modern impression materials is highly reliable.

Recently, technology has advanced to allow the construction of a virtual or digital three dimensional model using either a traditional impression or a digital impression taken directly from the dentition. Various manufacturers developed model scanning devices to accomplish this in different ways. Surface scanning of a stone model by a non-contact laser surface scanner is probably the most

commonly employed technique. This technique has the potential to introduce inaccuracies into the final digital model due to the necessity of using both an impression material and modeling material. Another method is Cone Beam Computed Tomography (CBCT) scanning of impressions. This method seeks to eliminate the possibility of loss of accuracy in the process of producing stone models from the impressions. These technologies still require the use of techniques and materials which will always have some degree of variation in accuracy.

When speaking about accuracy regarding digital models, the accuracy of the digital models themselves are not the only concern. Measurements between the two arches when digitally articulated are also clinically relevant and important to investigate. It has been found that while the scanning process can be sufficiently accurate for intra-arch measurements, often the bite registration scanned and used to produce digital articulation is not adequately accurate to make inter-arch measurements. In a study by White et al in 2010, inter-arch measurements made using digital models were found to have statistically significant differences from the measurements made on the original models. The authors concluded that the likely source of the error was the digital articulation performed by using data from a scanned wax bite registration. Another potential source of error in dimensional accuracy is the digital scanner itself and the differences in which data is acquired and manipulated. One study (Vlaar et al, 2006) compared the “digitizing quality” of laser scanners by scanning a precision ball of a known radius. Software analysis of the data compiled by the different

scanners found that accuracy corresponds to pixel distance of the sensors. It was noted that decreased distance between pixels on the physical sensor resulted in increased accuracy of the digital scan. Yet another performed by Kusnoto et al in 2002, assessed the reliability of a surface laser scanner by testing several different objects including a calibrated cylinder, a dental study model and a plaster facial model. This study found that the accuracy was clinically acceptable regardless of the type of object being scanned.

A digital model is only as useful as it is accurate though, and several studies have been performed to assess these types of models. In a study performed by Quimby et al, 2004, the researchers found that while linear measurements are generally reproducible, when a space analysis was completed on a digital model, there was a significant variance from that made on the dentoform. In a similar study, Garino and Garino, 2002, the investigators found that when attempting to perform measurement of tooth sizes, a significant difference is often found. The authors of this study concluded that the digital measurements may actually be more accurate due to the ability to reach points on the digital casts that are not able to be reached with the point of a caliper due to crowding, inclination, and rotation of teeth. In a similar study by Zilberman et al in 2003, the digital measurement of both tooth size and arch width were compared to stone models. In this case, it was found that the measurements made with digital calipers on stone models were more accurate and reproducible leading the authors to conclude that traditional methods were more accurate. However, the accuracy of digital models was deemed clinically acceptable. In

research performed by Santoro et al in 2003, the OrthoCAD system was evaluated by comparing digital measurements of both tooth size, overbite, and overjet to those made on the original plaster models. Statistically significant differences were found for tooth size and overbite but were considered clinically irrelevant. With the recent increase in the interest regarding the usefulness of digital models, a systematic review of the literature was performed by Fleming et al in 2011. It was found that measurements made from digital models were generally as accurate and reliable as measurements made from a plaster model and that the only statistically significant differences in measurements were, in practice, clinically insignificant.

With the profession's gradual acceptance of the quality and accuracy of digital models, there has been more interest in studies which apply the American Board of Orthodontics objective grading system to the virtual models. Several of these studies have been performed with differing conclusions. One such study was undertaken by Costalos et al. in 2005. The researchers found that only scoring of alignment and buccolingual inclination were significantly different from scoring of these categories on the stone models. They concluded that digital models might be acceptable for use in the ABO model examination. In a study performed by Okunami et al. in 2007, stone models were digitized using the OrthoCAD system and then scored using the ABO grading system. It was found that, at that time, the software was not adequate for scoring all parameters required by the ABO. Inevitable improvements in software would certainly

improve the likelihood of digital models becoming acceptable, if not preferred, for cases submitted to the American Board of Orthodontics for evaluation.

Another criticism of digital models has addressed the amount of time required to scan the model or impression and then manipulate the virtual models for study purposes. In 2007, Gracco et al set out to determine if there was an advantage in the time required by the operator to make measurements digitally versus manually. They found that accurate and reliable measurements were able to be made significantly faster using 3D digital models.

All this research has led to a discussion regarding the overall usefulness of digital models (Joffe, 2004, Peluso et al, 2004, Redmond, 2001). The obvious advantage is the elimination of the physical storage space that is required with traditional plaster models. Also, as a digital file which is backed up for safekeeping, there is no degradation in the materials or chance for damage of the models over time. As the digital world moves toward “cloud” or offsite storage of data and web-based software applications, these types of digital records could be available to a practitioner in any location that has web access. Clinically, the variations in treatment planning decisions using digital models have been studied by Whetten et al in 2006 with the conclusion that the digital models are a valid alternative to traditional plaster study models. In addition to these benefits, there may be applications for digital models which, to date, have not even been possible with plaster models. One such use would be for comparing digital orthodontic models taken during treatment and using software analysis to evaluate dentoalveolar changes; information which could previously only be

obtained through cephalometric superimposition (Cha et al, 2007). A study by Choi et al performed in 2010, tested the accuracy of this method using palatal superimposition of 3D digital models and found that tooth movements were able to be accurately measured using the anterior palatal surface as a reliable reference surface on which to superimpose.

Another use for digital models would be for model reproduction using the rapid prototyping manufacturing processes. It has been reported by Keating et al in 2008 that physical models were not able to be accurately reproduced to an acceptable level of detail using data acquired from a surface laser scanner. Also, in an unpublished research study performed in 2009 at the Tri-Service Orthodontic Residency Program, Lackland AFB, TX, it was found that while digital models are accurate enough for diagnosis and treatment planning purposes, they were not yet accurate enough to fabricate an orthodontic appliance using a prototyped model. Again, as both hardware and software technology advance, these type of applications are certainly becoming a reality.

This field is rapidly changing and the next generation of three dimensional digital orthodontic models involves direct oral scanning of the teeth and supporting structures by an optical device. This holds much promise as it could eliminate the potential inaccuracies inherent to traditional methods. There are several manufacturers which are already producing this technology and some that are integrated into newer treatment modalities. Some products which are now marketed are the SureSmile (OraMetrix, Richardson, TX) OraScanner, the Align Technologies (San Jose, CA) iTero iOC, and the 3Shape (Copenhagen,

Denmark) Trios. Systems such as SureSmile rely on the accuracy of the directly scanned models since this data is used to custom bend orthodontic wire using a robot. Similarly, the Align Technologies iTero iOC is currently being incorporated into the Invisalign™ treatment modality.

II. OBJECTIVES

A. Overall Objective.

This study aims to compare the dimensional accuracy of two methods of obtaining three dimensional digital orthodontic models. One method is by direct scanning of a resin model of reproducible occlusion with the Align Technologies iTero iOC scanning device. The other method is by indirect scanning of a PVS impression and bite registration of the same standard resin model using an ESM R700 model scanner. Arbitrary points were selected to allow intra-arch and inter-arch linear measurements. Multiple scans were accomplished and linear measurements were made. Statistical analysis was based on the percent change from the standard physical measurement made directly on the plastic model using digital calipers in an attempt to determine if there is a statistically significant difference in linear measurements made on the two sets of digital models.

B. Specific Hypothesis

There is no statistically significant difference in linear measurements made from the two different methods of obtaining the digital orthodontic models.

III. Materials and Methods

A. Experimental Design

Resin plastic models (Plastical, American Dental Supply, Allentown, PA) were fabricated from a silicone mold of the maxillary and mandibular McHorris Cusp-Fossa design models. Reference points were made in several locations on both the maxillary and mandibular models using a #4 carbide round bur to half its depth. These points were made on teeth surfaces to allow both intra-arch and inter-arch measurements to be performed. For intra-arch width measurement, points were placed on the tip of the mesiobuccal cusp of the maxillary first molars and were referred to as Mx1 for the maxillary right first molar and Mx2 for the maxillary left first molar. Reference points will also be made on the cusp tips of the maxillary canines (Figure 1). and were referred to as Cn1 for the maxillary right canine and Cn2 for the maxillary left canine. No marks will be made on the occlusal surfaces of the mandibular models (Figure 2). To facilitate inter-arch measurements, points will be placed on the buccal surfaces of both left and right, maxillary and mandibular first molars and referred to as M1 and N1 for the right side and M2, and N2 for the left side (Figure 3). The reference points placed on the maxillary and mandibular left central incisors were referred to as C1 and C2 (Figure 4). All inter-arch points were established in a vertical orientation at the height of contour as determined using the vertical laser positioning indicator on an iCat CBCT machine (Imaging Sciences International, Hatfield, PA) while the

models were on a stable base, perpendicular to the beam (Figure 5). Likewise, all intra-arch points were established in a horizontal orientation at the cusp tip using the horizontal laser positioning indicator of the iCat CBCT machine. The purpose of using the laser positioning indicator was to place the reference points on parallel planes. This was performed to provide some convenience when making linear measurements on the digital models since a cutting plane would be used to digitally section the models through the reference points. With the points placed on lines parallel to each other, the plane would only need to be scrolled anteriorly or posteriorly through the virtual model.

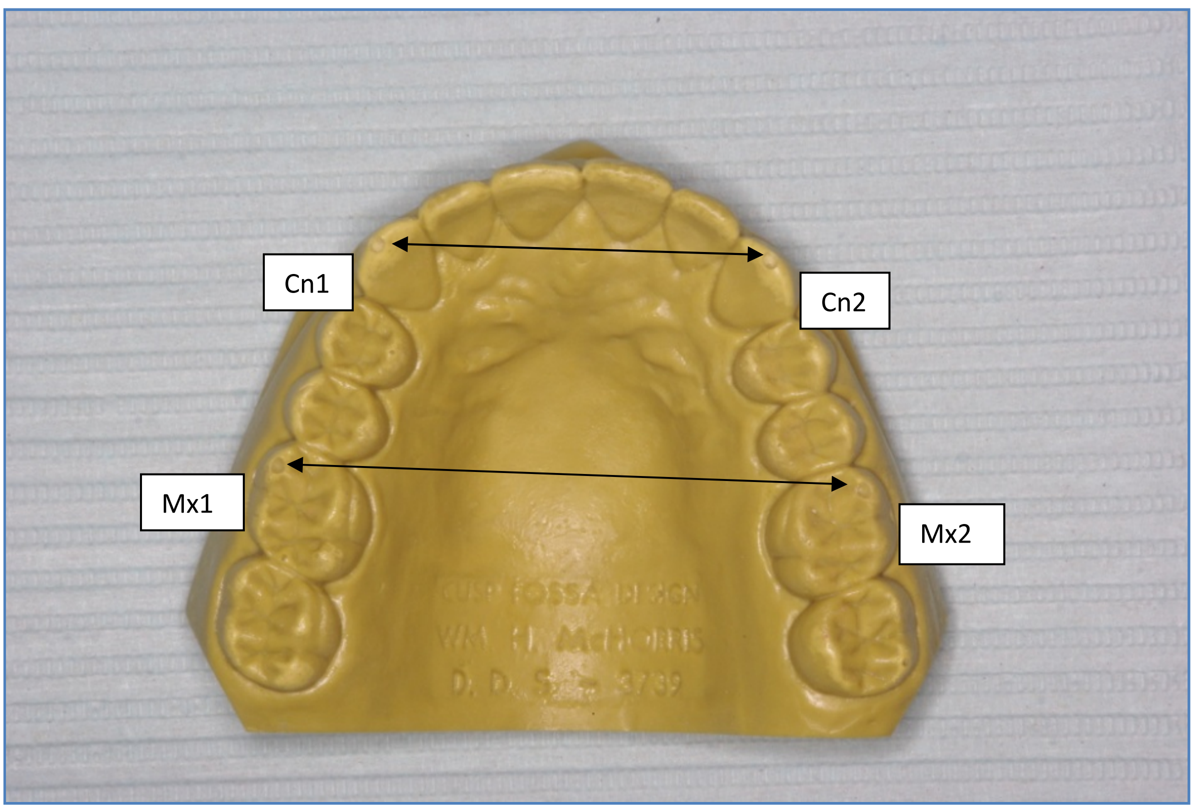

Figure 1. Maxillary Model, occlusal aspect, with reference points scribed.

Figure 2. Mandibular Model, occlusal aspect.

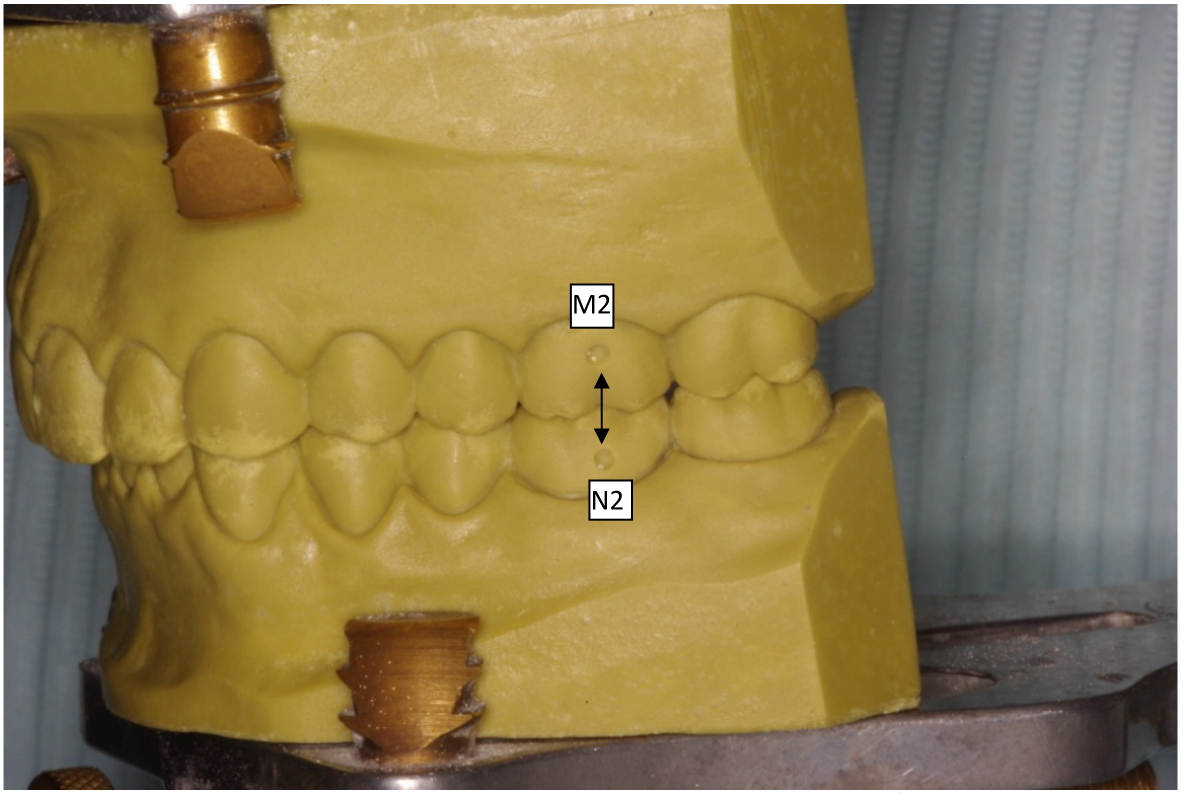

Figure 3. Occluded Maxillary and Mandibular models with reference points scribed at M2/N2.

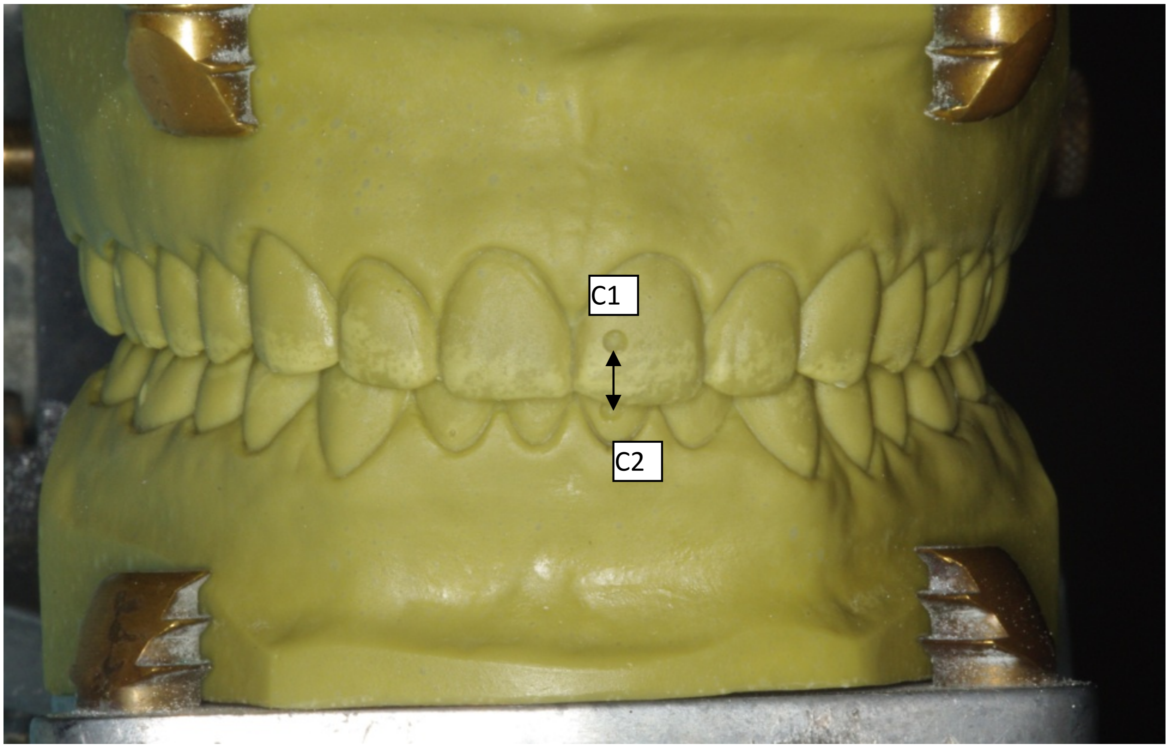

Figure 4. Occluded Maxillary and Mandibular models with reference points scribed at C1/C2.

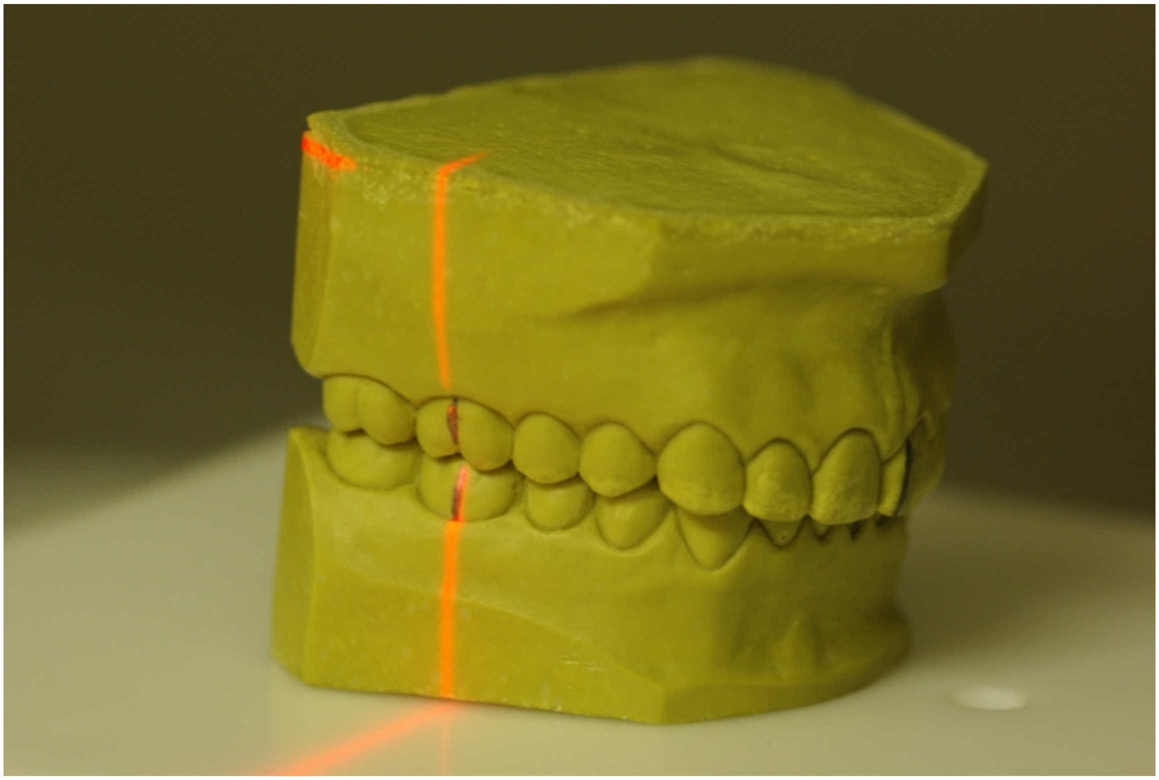

Figure 5. Vertical positioning of reference points on plastic occlusion models using laser positioning indicator on iCat CBCT.

After the maxillary and mandibular models had been prepared, they were mounted in maximum intercuspation in a hinge type articulator (Brevetto Galetti, Kerr Dental Laboratory Products , Orange, CA) and all adjustment knobs were tightened to avoid any movement from the established maxillomandibular occlusion. Vinyl polysiloxane (Aquasil Monophase, Dentsply Corporation, York, PA) maxillary and mandibular impressions of the prepared model were made (Figure 6). A bite registration (Figure 7). of the occlusion was made using a vinyl polysiloxane registration material (Regisil PB, Dentsply Corporation, York, PA). The maxillary and mandibular impressions were then scanned a total of sixteen times by the ESM R700 Model Scanner (ESM Digital Solutions, Dublin, Ireland)

(Figure 8). A scan of the Regisil bite registration allowed for a digital articulation of the virtual models using the proprietary software from 3Shape (Copenhagen, Denmark).

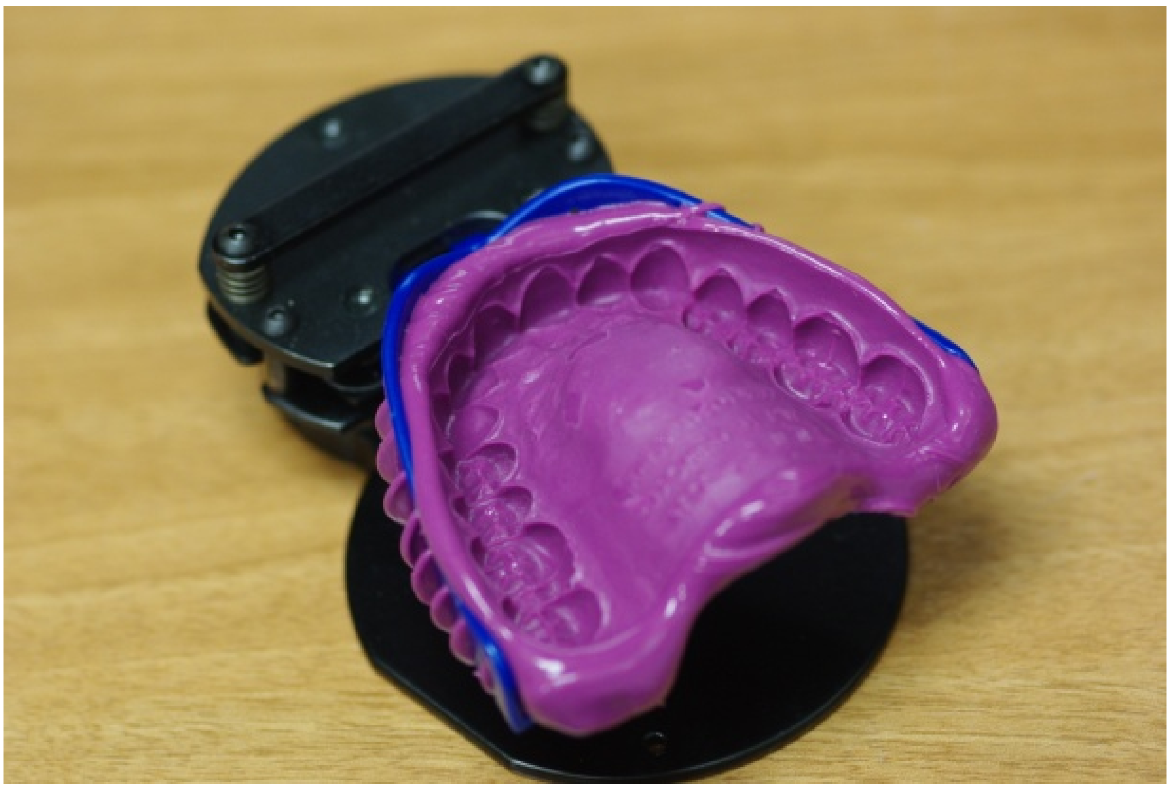

Figure 6. VPS impression ready for scanning by ESM R 700.

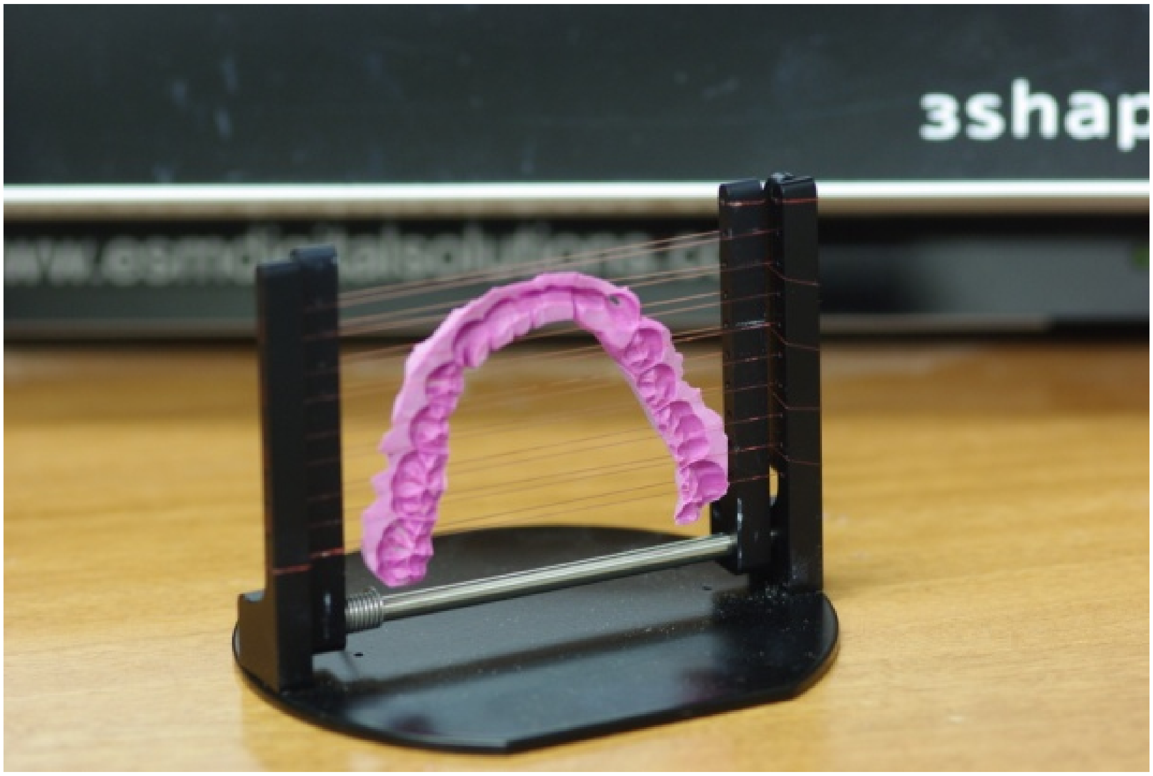

Figure 7. Trimmed bite registration ready for scanning by ESM R700.

Figure 8. ESM R700 Model Scanner

The iTero iOC intraoral scanner (Align Technology, San Jose, CA), was then employed to create a digital “impression” and subsequent digital orthodontic model of the mounted plastic models (Figure 9, 10). This scanning procedure also produced a digital “bite registration” by using data collected from a scan of the teeth in maximum intercuspation in the left and right molar region as well as the left and right premolar region. Proprietary software provided by the manufacturer (Cadent/Align Technologies, San Jose, CA) of the scanning unit was used to create the digital model and articulate the maxillary and mandibular models by utilizing the scan of the teeth in maximum intercuspation. The scanning procedure was repeated sixteen times to create sixteen sets of digital models.

Figure 9. ITero iOC intraoral scanning device.

Figure 10. Scanning the maxillary right buccal segment with the iTero iOC.

Linear measurements were then made using the reference points on the prepared models. It should be noted that in order to reduce the inaccuracies that could be encountered if attempting to measure from the center of each pair of reference points, it was decided that all measurements, whether direct or digital, would be performed from the point of greatest convexity of each reference dimple to the point of greatest convexity on the corresponding dimple (Figure 11).

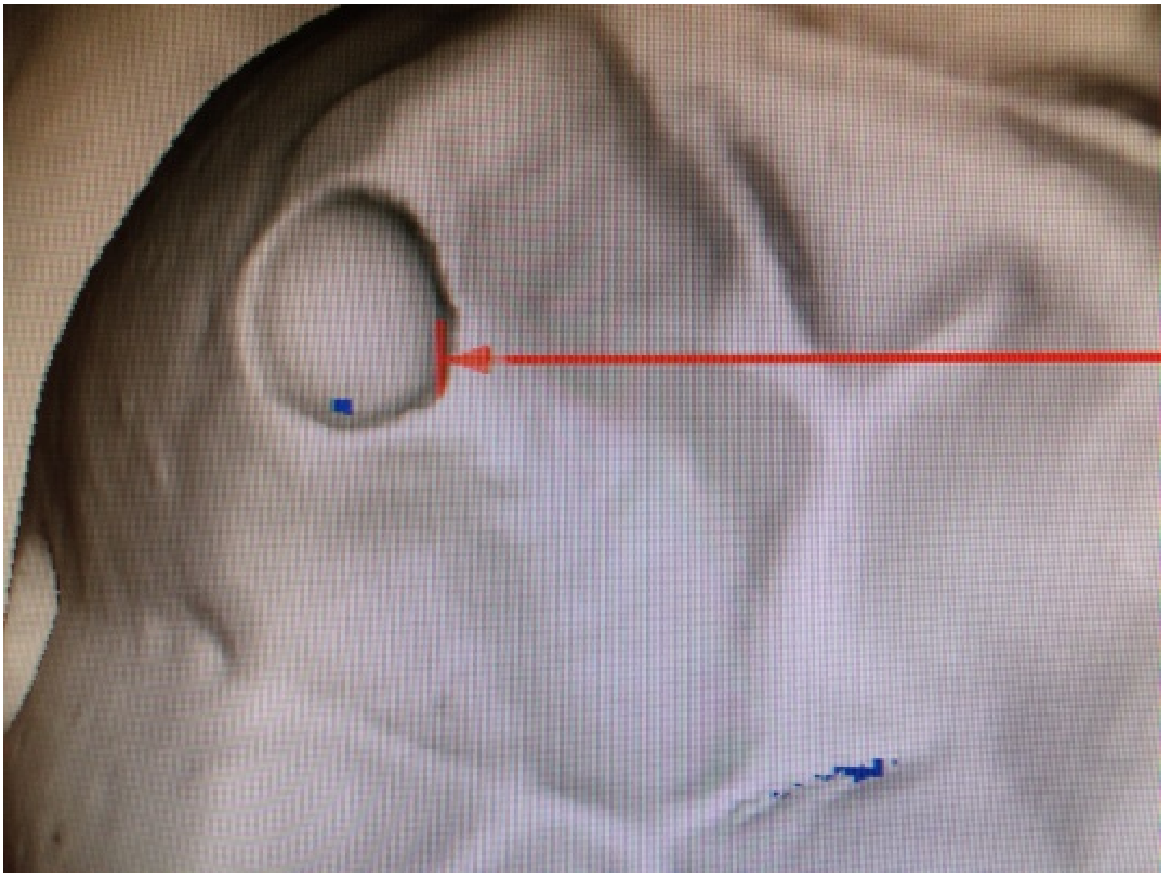

Figure 11. Digital scan from iTero iOC, demonstrating point of greatest curvature for measurements.

First, direct measurements were made on the control models using a digital caliper (Masel 4" orthodontic caliper, Philadelphia, PA) to record intercanine width (Cn1-Cn2), intermolar width (Mx1-Mx2), the distance from the right maxillary first molar to the right mandibular first molar (M1-N1), the distance from the left maxillary first molar to the right mandibular first molar (M2-N2), and the distance from the left maxillary central incisor to the left mandibular first molar. Each measurement was accomplished three times and the mean of the three measurements was calculated. This measurement was the standard from which the percent change of the digital measurements was calculated.

The digital measurements were then accomplished using the respective scanning device manufacturer's proprietary software. The ESM R700 Model

scanner employs OrthoAnalyzer software by 3Shape A/S (Copenhagen, Denmark) and the iTero iOC utilizes Cadent software (Align Technologies, San Jose, CA). Due to the difficulty that is sometimes encountered when attempting to make digital linear measurements on three dimensional digital models, it was determined that establishing a cross-sectional plane that intersected the reference points being measured would yield the most accurate linear measurements. For intra-arch and inter-arch measurements (inter-canine, inter-molar widths), a coronal plane was most useful (Figure 12). For the inter-incisal distance (maxillary central incisor to mandibular central incisor), a sagittal plane was most useful (Figure 13). All measurements were conducted by one rater.

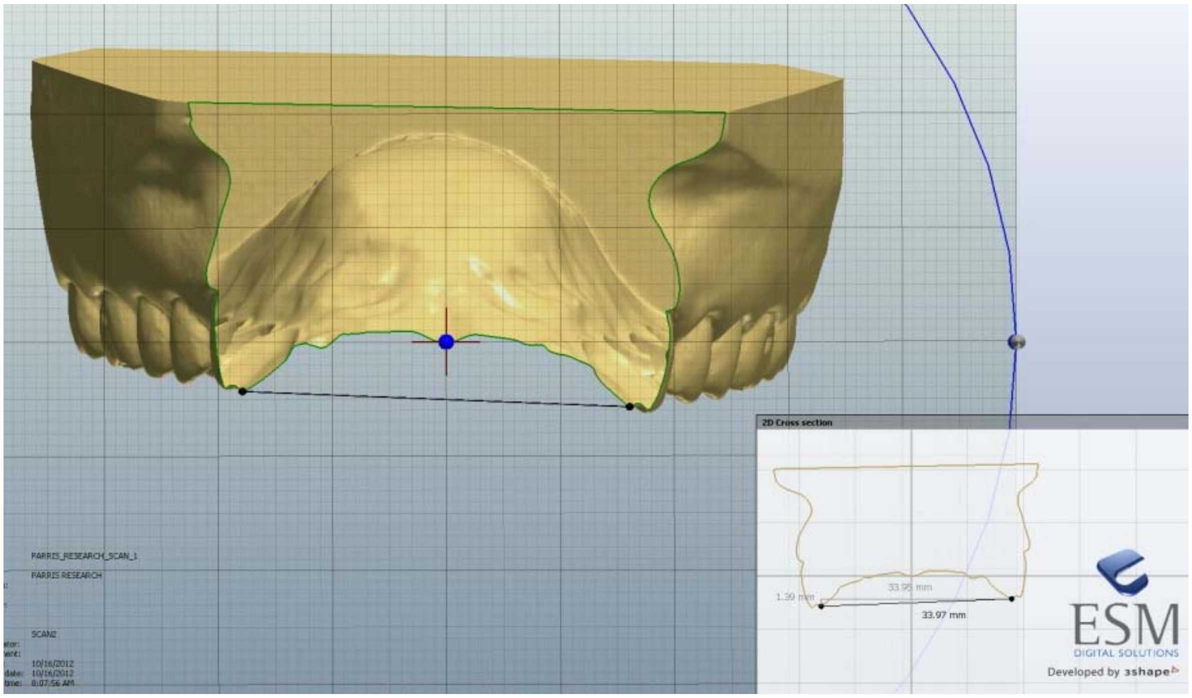

Figure 12. Coronal section of Maxillary model created by ESM software.

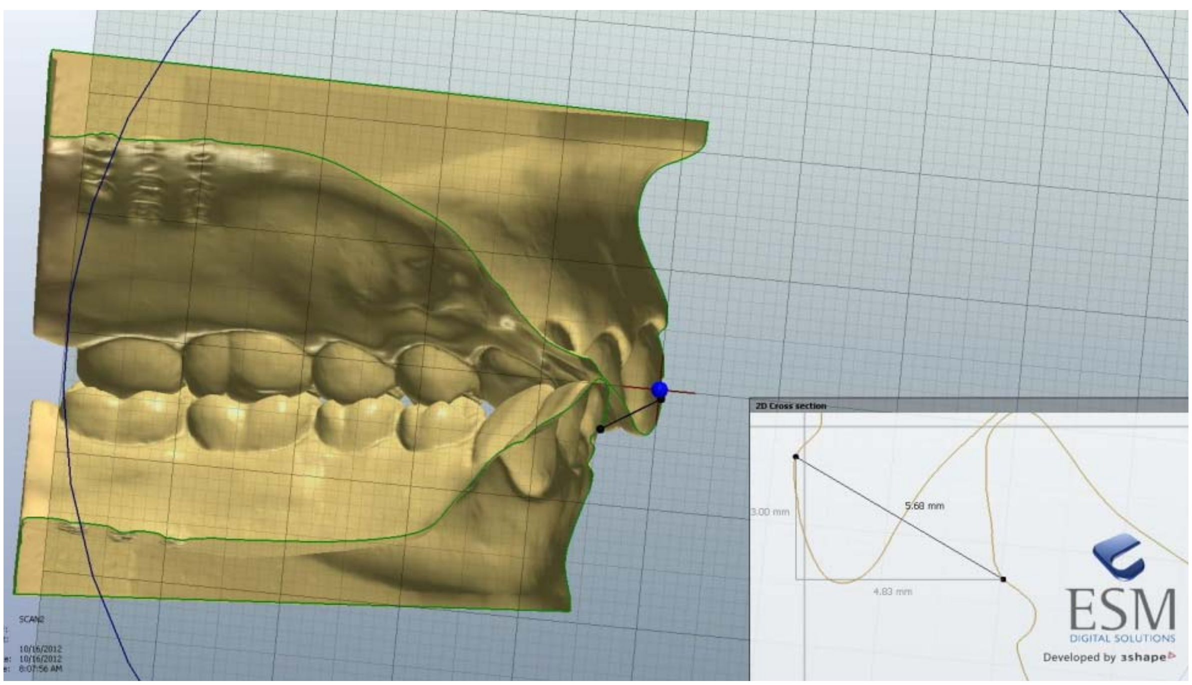

Figure 13. Sagittal section of Occluded Maxillary and Mandibular models created by ESM software.

IV. RESULTS

Statistical analysis was performed to assess a statistically significant difference in the measurements obtained digitally from those measured on the control models. Measurements made on the digital models were subtracted from the digital caliper measurements made on the resin control models to obtain an absolute difference. The percent change difference from the plastic model was then determined and a mean and standard deviation was calculated as displayed in Table 5. The percent change data from the two scanning methods was analyzed with a 2 way ANOVA to evaluate the effect of scanner type as well as measurement location (a=0.05). It was found that there was a significant difference between the measurements made digitally and those made on the physical casts based on both scanner type and location (P<.001) (Table 6). A separate 1-way ANOVA was then employed for each scanner type to determine the measurement locations at which the differences were significant. The 1-way ANOVA and subsequent Tukey's post-hoc test (Table 8) for the iTero iOC measurements found that there was a statistically significant difference at only the M1-N1 measurement (P<0.05). Conversely, the 1-way ANOVA and Tukey's post hoc test (Table 9) found that the ESM R700 showed significant differences in several locations. To compare the differences in each measurement category between the ESM R700 and iTero iOC, a series of unpaired t-tests were accomplished. After the Bonferroni correction, setting the p-value = 0.01, it was found that there were statistically significant differences between three of the five measurement locations.

V. DISCUSSION

The hypothesis that there is no statistically significant difference in linear measurements made on a three-dimensional (3D) digital orthodontic model obtained by direct scanning with an Align Technology (San Jose, CA) iTero iOC scanner compared to those obtained by indirect scanning with an ESM Digital Solutions (Dublin, Ireland) R700 model scanner must be rejected. The fact that significant differences were found in three out of the five measurements, as well as both an intra-arch measurement (Cn1-Cn2) and two inter-arch measurements (C1-C2 and M2-N2) makes it difficult to draw any conclusions regarding the accuracy of scanning method. While statistically significant differences were found in two of the three inter-arch linear measurements, a much greater difference as well as greater variability was found in the measurements obtained by the indirect method as indicated by the much lower standard deviations observed at every measurement location with direct scanning (Table 5.)

This study attempted to simulate different scanning methods that a clinician may employ regularly in a typical orthodontic practice for the production of digital orthodontic models. The main advantage to direct intraoral scanning of the dentition is the obvious elimination of potential error that is inherent in creating an impression of the maxillary and mandibular dentition and associated bite registration. We attempted to reduce the amount of potential error in several ways. First, by using a vinyl polysiloxane impression which has generally been accepted as highly dimensionally accurate, as well as highly accurate bite registration material (Shah et al, 2004). Second, instead of a standard typodont

with removable dentition, a solid model with predictable stable occlusion was preferred and fabricated using a dimensionally stable and durable material (Plastical Resin Model Material, American Dental Supply Inc., Allentown, PA). This allowed us to be reasonably confident that a reduction in interarch measurements was not due to flexure of the dentition or abrasion of occluding surfaces. Another attempt to control error was use of a solid hinge-type articulator which allowed a single path of closure.

Points of reference were selected to allow both intraarch and interarch measurements. It was determined that an anterior and posterior cross-arch measurement would be sufficient to assess the intra-arch accuracy of the digital models. Inter-arch accuracy was decided to be assessed using anterior and posterior points of reference as well, with the obvious necessity for both a left and right set of reference points to assess the accuracy of the digital articulation of the virtual models. While the traditional measurement of anterior overjet was considered due to its clinical usefulness, it was decided that points on the facial surface of the central incisors would be easier and more accurate to measure on the physical models and therefore yield a more accurate comparison with the two sets of virtual models.

Some studies have attempted to compare digital model accuracy by using third party software rather than the software provided with the scanning devices. This method allows differences in the models to be assessed objectively. While this method of comparison is very useful for some applications, a decision was made to use the manufacturer's software for two reasons. First, using third party

software would necessitate the exportation of the digital files in an .stl file format. This may have introduced uncertainty in the validity of the comparison since the files would have been converted from the proprietary file format that is the default for the respective scanning methods. Second, in an attempt to replicate the clinical practices that would be employed in a typical orthodontic office, it was important to use the software provided by the manufacturer. It is unlikely when producing digital models through either scanning method that an orthodontic office would convert the file format from what is produced by the manufacturer. Therefore, digital measurements were obtained using the analysis software included with each scanner. The ESM R700 employs 3Shape software (3Shape, Copenhagen, Denmark), while the iTero iOC employs software written by Cadent, a subsidiary of Align Technologies (San Jose, CA). While different software packages were employed, it was a goal to standardize the method in which each software was used to measure the digital models. In general, it was proposed that several techniques to improve accuracy of measurements could be built in to our protocol. First, reference points made on the surface of the resin models were made as dimples with a #4 round bur in a high speed handpiece. Instead of attempting to make measurements from the center of the dimple, which could be highly variable, we made measurements both physically and virtually from the points of greatest convexity on the corresponding dimples, a point which was much less variable and easier to define on the virtual models. Next, for both virtual model sets, a cross section through the models was made through the pair of reference points being measured and the measurement was

actually made on the 2-dimensional representation of that particular cross-sectional plane (Figure 12, 13). For the Cn1-Cn2, Mx1-Mx2, M1-N1, and M2-N2 measurements a coronal section was utilized. For the C1-C2 measurement, a sagittal section was employed.

While every attempt was made to minimize the introduction of measurement error through the scanning process there was one other variable that was unavoidable. While it is assumed that the vinyl polysiloxane impression and bite registration are sufficiently dimensionally stable and accurate, when producing the digital models via the indirect method with the ESM R700, the model must be articulated by manually identifying arbitrary points on both the maxillary and mandibular models and their corresponding points on the bite registration. At this point, the software takes over and produces a digital articulation of the two models. This differs from the method employed by the iTero iOC. Since scanning with the iTero is done directly on the dentition, or in this case the resin model, the bite registration is also taken using the patient/model in an occluded position. A scan of the occluded bite is recorded and the software then uses this data to articulate the two distinct models into an occluded set. For purposes of this study, four regions of the bite were recorded.

The results of this study demonstrated that both scanning methods were highly effective in producing accurate maxillary models. The highest mean percent change noted in intra-arch measurements was in the Cn1-Cn2 measurement made by the ESM which was only a 0.78% change with a standard deviation of 0.54. Both direct and indirect methods of scanning were able to

accurately produce a reliable inter-canine and inter-molar distance with all average measurements less than 1% change from the control model, demonstrating dimensional reliability in both the transverse and anterior-posterior planes. Conversely, when inter-arch measurements are studied, it was found that the direct scanning method was found to be overall more accurate, with two of three inter-arch measurements (C1-C2, M2-N2) found to be significantly more accurate than those made using the indirect method. It is the author's conclusion that the main reason for this discrepancy is the dependence of the indirect method on the bite registration for the digital articulation of the maxillary and mandibular models. While the material itself may be highly accurate when articulating a set of stone models, it seems that it is less able to provide enough data for digital articulation. In this study, the bite registration was prepared as a clinician would prepare a bite registration to be used on a set of physical models with much of the material trimmed away to allow for utilization of only the occluding surfaces. In retrospect, this method may not have been necessary and may have, in fact, reduced the accuracy of the articulation since much of the data that could have been used to match the maxillary and mandibular digital models to the bite registration may have been lost. This differs greatly from the way in which the iTero iOC software articulates the models using multiple scans of the buccal surfaces of the dentition while in articulation. A much greater amount of interocclusal data is provided to the software algorithm, resulting in a much more accurate representation of the occlusal relationship.

When utilizing the ESM R700 model scanner with physical models rather than impressions, the occluded models are scanned in a similar method to that of the iTero. While not part of this study, it may be found that the scanning of the occluded models produces more accurate inter-arch measurements. This however, would require the production of physical stone models prior to scanning, reducing some of the perceived benefit of scanning the impressions only.

Clinically, it may be found that neither method is significantly more efficient. It was noted that when making direct scans of the resin control model with the iTero iOC, the average time required to complete a full maxillary and mandibular scan and bite was around 15 minutes. This would seem to be only slightly longer than the amount of time required to make maxillary and mandibular impressions and a bite registration. Also, the clinician would need to then add in the time required to perform the actual scanning of the impressions and digital articulation. It should also be remembered that the 15 minute direct scan time was based on the scanning of a static resin model in which the rather bulky scanning unit could be held at what might conceivably be very difficult angles if being used on a live patient. Therefore, it would most likely take significantly more clinical time to produce the direct scanned digital models.

When comparing these two methods of digital model production, it should be noted that there is great deal of difference in pricing of the scanning units. The iTero iOC, at this time, is many times the cost of the ESM R700. While the iTero does eliminate the need to maintain an inventory of impression material, trays,

and other associated materials, it would be hard to argue that the iTero is a cost effective alternative. One of the main reasons supporting the use of the iTero iOC for direct digital impressions is the perceived improvement in patient comfort and convenience that comes with the elimination of impression materials. Another benefit is direct submission of digital models to orthodontic laboratories for the fabrication of appliances. Notably, Align Technologies has begun to utilize the directly scanned digital models for the production of Invisalign™ aligners. Many other orthodontic laboratories are embracing this technology as well, accepting digital submission of cases via the internet for fabrication of a number of appliances. Often, the laboratory is employing a three-dimensional printing capability to allow for creation of a physical model on which the appliances are fabricated. This can significantly reduce the amount of transit time required as well as reducing opportunities for damage, loss or most importantly, inaccuracies.

The technology associated with the production of digital impressions and subsequent digital models is progressing at a rapid rate and may soon become the standard of care as the quality increases, price decreases, and ease of use becomes mainstream. The benefits of durability, storability, transferability and portability will most likely lead practitioners to “go digital” when it comes to making impressions whether for diagnostic purposes, indirect bonding trays, clear aligners or other orthodontic appliances. This study has shown that while there are still some differences in the variability expected with indirect vs. directly

produced digital models, both methods would likely be clinically acceptable for most orthodontic applications.

VI. CONCLUSIONS

1. There is a statistically significant difference in the percent change differences of inter-arch and intra-arch measurements made on digital models produced by a direct and indirect scanning method.

2. While it appears that the direct scanning method may be slightly more accurate in intra-arch measurements, its greatest strength lies in inter-arch measurement reliability where there is much less variability and no bite registration is necessary.

3. Clinically, both methods of producing digital models are acceptable and each method has its own inherent benefits.

APPENDIX A.

Table1. Raw Data (ESM R700 and iTero iOC)

ESM Measurements	Cn1-Cn2	Mx-Mx2	C1-C2	M1-N1	M2-N2
1	33.68	51.87	5.8	6.8	6.31
2	34.71	52.24	5.69	7.1	7.03
3	34.68	51.89	5.72	6.43	6.35
4	34.01	51.45	5.85	6.83	6.16
5	34.06	51.66	5.91	6.96	6.39
6	34.52	52.01	6.12	7.08	6.51
7	34.23	51.95	5.71	6.83	6.34
8	34.66	51.98	6.02	7.05	6.61
9	33.81	51.39	5.99	7.14	7.01
10	34.12	51.73	5.68	6.96	6.83
11	34.37	51.63	5.99	7.03	6.76
12	34.23	51.98	5.83	6.99	6.81
13	33.98	51.26	6.11	7.12	6.93
14	34.36	51.74	5.93	7.06	7.01
15	34.56	51.82	6.2	7.18	6.93
16	34.49	51.89	6.15	7.21	7.04

iTero Measurements	Cn1-Cn2	Mx-Mx2	C1-C2	M1-N1	M2-N2
1	34.45	51.90	5.73	6.52	6.15
2	34.46	51.94	5.68	6.51	6.12
3	34.41	51.86	5.65	6.50	6.24
4	34.43	51.80	5.74	6.62	6.15
5	34.42	51.92	5.63	6.67	6.14
6	34.37	51.91	5.69	6.62	6.19
7	34.45	51.74	5.63	6.56	6.19
8	34.46	51.83	5.68	6.60	6.18
9	34.25	51.94	5.78	6.53	6.14
10	34.40	51.92	5.65	6.64	6.22
11	34.41	51.87	5.73	6.61	6.20
12	34.40	51.67	5.70	6.58	6.22
13	34.35	51.93	5.69	6.64	6.16
14	34.42	51.91	5.73	6.66	6.19
15	34.42	51.82	5.76	6.44	6.21
16	34.40	51.87	5.66	6.53	6.15

Table 2. Absolute Changes (ESM R700 and iTero iOC)

(ESM) Change from Master in mm.	Cn1-Cn2	MX1-MX2	C1-C2	M1-N1	M2-N2
1	0.69	0.07	0.11	0.04	0.11
2	0.34	0.30	0.00	0.34	0.83
3	0.31	0.05	0.03	0.33	0.15
4	0.36	0.49	0.16	0.07	0.04
5	0.31	0.28	0.22	0.20	0.19
6	0.15	0.07	0.43	0.32	0.31
7	0.14	0.01	0.02	0.07	0.14
8	0.29	0.04	0.33	0.29	0.41
9	0.56	0.55	0.30	0.38	0.81
10	0.25	0.21	0.01	0.20	0.63
11	0.00	0.31	0.30	0.27	0.56
12	0.14	0.04	0.14	0.23	0.61
13	0.39	0.68	0.42	0.36	0.73
14	0.01	0.20	0.24	0.30	0.81
15	0.19	0.12	0.51	0.42	0.73
16	0.12	0.05	0.46	0.45	0.84

(iTero) Change from Master in mm.	Cn1-Cn2	MX1-MX2	C1-C2	M1-N1	M2-N2
1	0.08	0.04	0.04	0.24	0.05
2	0.09	0.00	0.01	0.25	0.08
3	0.04	0.09	0.04	0.26	0.04
4	0.06	0.14	0.05	0.14	0.05
5	0.04	0.02	0.06	0.09	0.06
6	0.01	0.03	0.01	0.14	0.01
7	0.08	0.20	0.06	0.20	0.01
8	0.09	0.11	0.00	0.16	0.02
9	0.13	0.01	0.09	0.23	0.06
10	0.03	0.02	0.04	0.12	0.02
11	0.04	0.08	0.04	0.15	0.00
12	0.02	0.27	0.01	0.18	0.02
13	0.02	0.01	0.00	0.12	0.04
14	0.05	0.04	0.04	0.10	0.01
15	0.04	0.12	0.07	0.32	0.01
16	0.03	0.07	0.03	0.23	0.05

Table 3. Descriptive Statistics. Percent change from standard model, mean percent change and standard deviation. (ESM R700)

% Change from Master (ESM)	Cn1-Cn2	MX1-MX2	C1-C2	M1-N1	M2-N2
1	2.02	0.14	1.99	0.59	1.77
2	0.98	0.57	0.06	5.03	13.39
3	0.89	0.10	0.59	4.88	2.42
4	1.06	0.95	2.87	1.04	0.65
5	0.91	0.55	3.93	2.96	3.06
6	0.43	0.13	7.62	4.73	5.00
7	0.42	0.01	0.41	1.04	2.26
8	0.83	0.07	5.86	4.29	6.61
9	1.64	1.07	5.33	5.62	13.06
10	0.74	0.41	0.12	2.96	10.16
11	0.01	0.60	5.33	3.99	9.03
12	0.42	0.07	2.52	3.40	9.84
13	1.14	1.32	7.44	5.33	11.77
14	0.04	0.39	4.28	4.44	13.06
15	0.54	0.24	9.02	6.21	11.77
16	0.34	0.10	8.14	6.66	13.55
mean	0.78	0.42	4.09	3.95	7.96
standard deviation	0.54	0.40	3.02	1.84	4.77

Table 4. Descriptive Statistics. Percent change from standard model, mean percent change and standard deviation. (iTero iOC)

% Change from Master (iTero)	Cn1-Cn2	MX1-MX2	C1-C2	M1-N1	M2-N2
1	0.22	0.08	0.73	3.58	0.79
2	0.26	0.01	0.15	3.67	1.23
3	0.11	0.17	0.66	3.85	0.66
4	0.16	0.28	0.90	2.01	0.79
5	0.12	0.04	1.01	1.32	0.94
6	0.02	0.06	0.11	2.04	0.13
7	0.22	0.39	1.03	2.93	0.13
8	0.26	0.22	0.06	2.31	0.37
9	0.37	0.01	1.55	3.43	1.00
10	0.08	0.04	0.66	1.80	0.37
11	0.11	0.15	0.78	2.20	0.02
12	0.07	0.52	0.25	2.62	0.29
13	0.07	0.03	0.02	1.76	0.60
14	0.14	0.07	0.69	1.43	0.21
15	0.13	0.23	1.31	4.67	0.16
16	0.07	0.14	0.56	3.34	0.76
mean	0.15	0.15	0.66	2.69	0.53
standard deviation	0.09	0.15	0.45	0.98	0.37

Table 5. Mean % change and standard deviation for both scanning methods by measurement location.

	ESM Mean % change(SD)	iTero Mean % change(SD)
Cn1-Cn2	0.78(0.54)	0.15(0.09)
MX1-MX2	0.42(0.40)	0.15(0.15)
C1-C2	4.09(3.02)	0.66(0.45)
M1-N1	3.95(1.84)	2.69(0.98)
M2-N2	7.96(4.77)	0.53(0.37)

Table 6. Results of 2-Way ANOVA comparing the effects of scanning method and measurement location.

Tests of Between-Subjects Effects
Dependent Variable: PERCENT

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	941.124(a)	9	104.569	28.263	.000
Intercept	730.769	1	730.769	197.512	.000
SCANNER	271.649	1	271.649	73.421	.000
LOCATION	387.835	4	96.959	26.206	.000
SCANNER * LOCATION	281.640	4	70.410	19.030	.000
Error	554.980	150	3.700		
Total	2226.872	160			
Corrected Total	1496.104	159			

a R Squared = .629 (Adjusted R Squared = .607)

Table 7. Results of Tukey's Post Hoc test analyzing results of 2-Way ANOVA

PERCENT Tukey HSD				
LOCATION	N	Subset		
		1	2	3
MX1	32	.2863		
Cn1	32	.4631		
C1	32		2.3744	
M1	32		3.3166	3.3166
M2	32			4.2453
Sig.		.996	.286	.301

Means for groups in homogeneous subsets are displayed.
Based on Type III Sum of Squares
The error term is Mean Square(Error) = 3.700.

a Uses Harmonic Mean Sample Size = 32.000.

b Alpha = .05.

Table 8. Results of Tukey's Post Hoc test analyzing results of 1 way ANOVA for iTero iOC

PERCENT Tukey HSD			
	N	Subset	
LOCATION		1	2
Cn1	16	.1506	
MX1	16	.1525	
M2	16	.5281	
C1	16	.6544	
M1	16		2.6850
Sig.		.054	1.000

Means for groups in homogeneous subsets are displayed.
Based on Type III Sum of Squares
The error term is Mean Square(Error) = .266.

a Uses Harmonic Mean Sample Size = 16.000.

b Alpha = .05.

Table 9. Results of Tukey's Post Hoc test analyzing results of 1-Way ANOVA for ESM R700.

PERCENT Tukey HSD				
	N	Subset		
LOCATION		1	2	3
MX1	16	.4200		
Cn1	16	.7756		
M1	16		3.9481	
C1	16		4.0944	
M2	16			7.9625
Sig.		.996	1.000	1.000

Means for groups in homogeneous subsets are displayed.
Based on Type III Sum of Squares
The error term is Mean Square(Error) = 7.133.

a Uses Harmonic Mean Sample Size = 16.000.

b Alpha = .05.

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